

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Carl J. PEPINE et al.

Title:

COMBINATION DRUG THERAPY FOR TREATING HYPERTENSION

Appl. No.:

10/816,461

Filing Date: 04/01/2004

Examiner:

Unassigned

Art Unit:

1614

## INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Nov. 22, 2004

**FOLEY & LARDNER LLP** 

Customer Number: 22428 Telephone:

(202) 672-5569

Facsimile:

(202) 672-5399

Stephen B. Maebius Attorney for Applicant Registration No. 35,264

Sigh Brak

MODIFIED PTO/SB/08 (08-00)

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number. Substitute for form 1449B/PTO Complete if Known **Application Number** 10/816,461 INFORMATION DISCLOSURE 04/01/2004 STATEMENT BY APPLICANT Filing Date Carl J. Pepine **First Named Inventor** NOV 2 3 2004 1614 **Group Art Unit** (use as many sheets as necessary) **Examiner Name** Unassigned Sheet 1 of 1 Attorney Docket Number 028685-0104

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>€</sup>		
	A1	MESSERLI et al., "Long-term Cardiovascular Consequences of Diuretics vs Calcium Channel Blockers vs Angiotensin-Converting Enzyme Inhibitors," <u>JAMA</u> , April 23/30, 2003, pp. 2067-2068, Vol. 289, No. 16, American Medical Association			
	A2	Heart Diseases and Stroke Statistics – 2003 Update, 2002, pp. 1-42, American Heart Association			
	А3	Heart Diseases and Stroke Statistics 2004 Update, 2003, pp. 1-48, American Heart Association			

Examiner	Date	·
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.